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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,321	11/20/2003	Veronique Bailly	13751-032001	3659

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,321	BAILLY ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10 and 12-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Yunsoo Kim, Art Unit 1644, Technology 1600.

2. Claims 1-22 are pending,

3. Applicants' election without traverse of Group I, claims 1-9 and 11 drawn to an antibody, hybridoma and composition is acknowledged.

Accordingly, claims 10 and 12-22 are withdrawn from further consideration by the examiner 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-9 and 11 drawn to an antibody, hybridoma and composition are under consideration in the instant application.

4. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing amino acid sequence disclosures

5. Applicants claim for domestic priority under 35. U.S.C. 119(e) is acknowledged.

6. The application is required to be reviewed and all spelling, and like errors corrected.
□ appears in place of hyphen (i.e. ¶ 0026 and 0046).

7. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

8. Claims 1-5 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter; a product of nature.

Claims 1-5 as written, do not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-7 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody that binds to an epitope within SEQ ID NO:1, , does not reasonably provide enablement for antibody derivative or antigen binding polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the antibody derivative or antigen-binding polypeptide recited in the instant claims. A person of skill in the art would not know which molecule that contains chemical moiety, variant, analog, or fragment that may improve the molecule's solubility, absorption, or biological half-life or may decrease the toxicity of the molecule. There is insufficient guidance to direct a person of skill in the art to select particular antibody derivative or antigen-binding polypeptide. Without detailed direction as to which molecule is essential to improve the molecule's solubility, absorption, or biological half-life or may decrease the toxicity of the molecule, a person of skill in the art would not be able to determine which peptide are antagonistic without undue experimentation.

Minor structural differences among structurally related compounds can result in substantially different in solubility, adsorption, or biological activities. Therefore, structurally unrelated compounds comprising antibodies, antibody derivative or antigen-binging polypeptides would be expected to have greater differences in their activities. Rudikoff et al. (Proc. Nat. Acad. Sci., USA, 1982, 79:1979-1983) discloses that even a single amino acid change in the sequence of a monoclonal antibody can alter the antibody's binding activity (see Abstract in particular).

Furthermore, Applicant has no working examples demonstrating antibody derivative or antigen-binding polypeptides which improve the molecule's solubility, absorption, or biological half-life or may decrease the toxicity of the molecule.

Accordingly, the specification is not enabling for antibody derivative or antigen binding polypeptide because the specification does not adequately disclose how to make antibody derivative or antigen-binding polypeptide that are functional for practice of the claimed invention.

11. Claims 3, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The hybridoma ABE3 recited in ATCC Accession number PTA-3350 is essential to the claimed invention. The reproduction of antibodies from the disclosed hybridoma is an extremely unpredictable event. The hybridoma ABE3, disclosed on page 18 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridomas, and it is not apparent if the hybridomas are readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hyrbridomas have been deposited under the Budapest Treaty **and that the hybridomas/antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808**. Further, the record must be clear that the deposit will be maintained in a

public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the hybriodoma described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
January 14, 2005

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